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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,493	06/22/2001	Gregor Cevc	500.1013	7718
21874	7590	02/02/2005	EXAMINER	
EDWARDS & ANGELL, LLP			COE, SUSAN D	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	

1654

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/887,493	Applicant(s) CEVC, GREGOR	
	Examiner Susan D. Coe	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,9,12-14,21-24,35,39-41,44-46 and 51-85 is/are pending in the application.
- 4a) Of the above claim(s) 52,53,55-75 and 77-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,9,12-14,21-24,35,39-41,44-46,51,54,76 and 83-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/30/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 12, 2004 has been entered.
2. Claim 4 has been cancelled.
3. Claims 1-3, 5, 6, 9, 12-14, 21-24, 35, 39-41, 44-46, and 51-85 are currently pending. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. In Paper No. 9, dated October 10, 2002, applicants elected a cellulose derivative for species A, BHT for species B, methylparaben for species C, and clobetasol for species D without traverse.
5. Claims 52, 53, 55-75 and 77-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.
6. Claims 1-3, 5, 6, 9, 12-14, 21-24, 35, 39-41, 44-46, 51, 54, 76 and 83-85 are examined on the merits solely in regards to the elected species.

Claim Objections

7. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

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claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 contains the same limitations that are present in item 2 of claim 1.

Claim Rejections - 35 USC § 112

8. Claim 85 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is indefinite because it is not clear what alcohols are considered to meet the limitation of “short chain alcohols.”

Claim Rejections - 35 USC § 103

9. Claims 1-3, 5, 6, 9, 12-14, 21-24, 35, 39-41, 44-46, 51, 54, 76 and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over German Pat. No. 44 47 287 C1 in view of US Pat. No. 5,322,685 and Cevc et al. (Journal of Controlled Release (1997), vol. 45, pp. 211-226 - published April 1997 (see table of contents enclosed)).

With the inclusion of Cevc, this is technically a new ground of rejection. However, applicant's arguments regarding the 103 rejection over DE '287 and US '685 will be discussed in light of Cevc. Applicant argues that DE '287 does not teach or suggest a formulation where the amount of corticosteroid used is above 0.1% by weight. Applicant argues that a person of ordinary skill in the art would not arrive at a dosage of this amount because it is known in the art that higher dosages of topical corticosteroids cause side effects. Applicant provides the review article by Reazzini to show that determining the correct dosage of a topical corticosteroid that

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does not cause side effects is difficult. However, the reference itself states that hypersensitivity to topical corticosteroids is prevalent when dosages are used that are between 0.2 and 5% (see page 52, second column, first full paragraph). Thus, this reference shows that a dosage of below 0.2% is a safe dosage for a topical corticosteroid. Therefore, using these dosages in the topical composition of DE '287 would have been obvious because they are known to be safe dosages.

Applicant also argues that currently FDA approved topical corticosteroid compositions do not contain more than 0.05% of the corticosteroid. However, applicant only provides data showing formulations for clobetasol, this does not translate to all topical corticosteroids. In addition, there is no explanation why a person of ordinary skill in the art would not be motivated to increase the dosage of clobetasol especially in view of Rezzini disclosure that dosages below 0.2% do not produce side effects.

Furthermore, Cevc teaches using steroids in Transfersomes at a ratio of 1/10 to 1/100 of drug to lipid (see page 213 "Materials and Methods"). As discussed in previous Office actions, Transfersomes are the lipid composition taught by DE '287. Thus, Cevc shows that it was known in the art at the time of the invention to include steroids in the amounts claimed by applicant. Thus, a person of ordinary skill in the art would be motivated to use these amounts in the Transfersomes of DE '287.

Applicant also argues that DE '287 does not teach the use of an antioxidant or a microbiocide. However, on page 25, second paragraph, DE '287 teaches using BHT (applicant's elected species for the antioxidant) and benzyl alcohol (a short chain alcohol microbiocide as defined by applicant on page 12, line 15 of the specification). Thus, DE '287 does teach using antioxidants and microbiocide. The reference does not specifically teach using these ingredients

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in amounts to yield the effects claimed by applicant. However, a person of ordinary skill in the art would routinely optimize the amount of these ingredients to yield the most stable product.

This would reasonably lead to a product having the effects claimed by applicant.

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.



1-28-05

Susan D. Coe
Primary Examiner
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